FEB 13 2014

Section 5: 510(k) Summary:

This summary of 510k safety and effectiveness information is being submitted
In accordance with the requirements of 21CFR 807.92

Submitter & Foreign Manufacture Identification

Zhejiang Jiafeng Electrical & Mechanical Co., Ltd
No. 128 Jinxiu Road, Luoxing District,
Jiashan, Zhejiang, 314100 China
Submitter's FDA Registration Number: N/A

US Agent and Contact Person

Charles Shen
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Date of Summary: June 01, 2013

Device Name:	
Proprietary Name:	Manual Wheelchair Model SY100-MA02 (02A & 02B) and Model SY100-MA06 (or other clients private labeling)
Common Name:	Mechanical Wheelchair
Classification Name:	Wheelchair, Mechanical
Device Classification:	1
Regulation Number:	21 CFR 890.3850
Panel: General	Physical Medicine
Product Code:	IOR

Predicate Device Information:
(1) K062311, "KARMA Manual Wheelchair, Budget 800", manufactured by "KARMA Medical Products Co., Ltd."

Device description:

A mechanical wheelchair is a chair with wheels, designed to be a replacement for walking, where it is propelled by the seated occupant turning the rear wheels by hand. There are also handles behind the seat for someone else to do the pushing. Wheelchairs are used by people for whom walking is difficult or impossible due to illness, injury, or disability.

The Manual Wheelchairs Model SY100-MA02 (02A & 02B) and Model SY100-MA06 (or other clients private labeling) are user propelled, manually operated folding wheelchairs that are indicated for use indoors and outdoors, over smooth surfaces (all standard indoor flooring surfaces, concrete, asphalt and packed dirt) that are free of large obstacles and inclines greater than **8** degrees. Each consists of four wheels, a mechanical steel frame and nylon upholstery that is ignition resistant. The device is designed to be lightweight and foldable, and can be dissembled. In both models, both rear and caster wheels use solid tires.

The model SY100-MA02 has two sub-models (02A & 02B) which both has a physical dimension of 1025 (depth) x 661 (width) x 920 (height) mm, with the seat itself has a dimension of 408 (depth) x 440 (width) x 455 (height) mm. The device has a weight capacity of 130 kilograms.

Sub-model MA02A uses hard plastic back wheels and weighs approximately 16.5 kilograms. Sub-model MA02B uses wired steel wheels and weighs 13.8 kilograms. Both sub-models are dark green in color.

Model SY100-MA06 has a physical dimension of 1026 (depth) x 651 (width) x 860 (height) mm, with the seat itself has a dimension of 394 (depth) x 374 (width) x 482 (height) mm, and a weight capacity of 100 kilograms, and weighs approximately 15.2 kilograms.

Intended Use:
The device is intended for medical purposes to provide mobility to persons restricted to a sitting position. It is designed for use indoors and outdoors, over smooth surfaces (all standard indoor flooring surfaces, concrete, asphalt and packed dirt) that are free of large obstacles and inclines greater than **8** degrees.

Comparison to Predicate Devices
The Manual Wheelchair Model SY100-MA02 (02A & 02B) and Model SY100-MA06 (or other clients private labeling) are compared with the following Predicate Devices in terms of intended use, design, material, specifications, and performance.

(1) K062311, "KARMA Manual Wheelchair, Budget 800", manufactured by "KARMA Medical Products Co., Ltd."

The following table shows similarities and differences of use, design, and material between our devices and the predicate device.

Table 5.1: Comparison of Intended Use, Design, and Material

Description	Our Devices	Predicate Device (K062311)
Indication for Use	The device is intended for medical purposes to provide mobility to persons restricted to a sitting position. It is designed for use indoors and outdoors, over smooth surfaces (all standard indoor flooring surfaces, concrete, asphalt and packed dirt) that are free of large obstacles and inclines greater than **8** degrees.	The device is intended for medical purposes to provide mobility to persons restricted to a sitting position.
Basic Design	Four wheels, a mechanical steel frame and nylon upholstery that is flame resistant.	Same
Materials	Steel and flame resistant fabrics	Same
Powder	Mechanical	Same
Dimension	SY 100 MA02 (02A & 02B):1025 x 661 x 920 mm (depth x width x height) SY 100 MA06:1026 x 651 x 860 mm (depth x width x height)	1080 x 610 x 432 mm (depth x width x height)
Armrest	Arm Pad/Non Flip Back/Height Adjustable	Arm Pad/Flip Back/ Not Height Adjustable
Rear Axle	Offset Axle, Quick Release Axle	Same
Back Wheel	61 cm (=24 inch)	24 inch
Casters	SY 100 MA02 (02A & 02B): 20 cm (=8 inch) SY 100 MA06: 15 cm (= 6 inch)	8 inch
Wheel Lock	Pull to Lock	Same
Weight Capacity	SY 100 MA02: 130 Kg SY 100 MA06: 100 Kg,	115 Kg
Weight	SY 100 MA02A: 16.5 Kg (plastic wheel) SY 100 MA02B: 13.8 Kg (netted steel wheel) SY 100 MA06: 15.2 Kg	14.44 and 14.64 Kg
Color	SY 100 MA02 (02A & 02B): Dark Green SY 100 MA 06: Black	Black/Blue

Our devices and the predicate device are almost identical in terms of all areas described in the above table (*Table 5.1*). Our Indications for Use consists of two sentences. The first sentence is identical to the predicate device, the second sentence explains in detail of the surface suitable for use. This indication provides users better instruction as to what is the safe road condition for the wheelchair, and protects the users better.

In terms of design, in addition to small size differences, the first slight difference is the armrest design. The armrests in predicate device are able to flip back and not height adjustable, while in our devices they are not able to flip back, but are able to be dissembled, and are height adjustable for the comfort of passenger. Detailed drawings of the armrest design can be found in Section 11. The second difference is that SY 100-MA 02 (02A & 02B) has a secondary hand brake located in the push handle area for the convenient use by the care providers. These minor differences with the predicate device don't affect the function or indications for use of the device.

The following table shows similarities and differences of the performance between our devices and the predicate device. Tests were conducted following the recommended procedures outlined in the respective consensus standards, and results for Manual Wheelchair Model SY100-MA02 (02A & 02B) and Model SY100-MA06 (or other clients private labeling), manufactured by "Zhejiang Jiafeng Electrical & Mechanical Co., Ltd." met all relevant requirements in the test standards, our internal specifications, and are comparable to the predicate device.

Table 5.2: Comparison of Physical, Biocompatibility and Performance Testing

Description	Our Devices	Predicate Device (K062311)
Static Stability	Meets ISO 7176-1:1999	Met ISO 7176 Wheelchair Standards
Effectiveness of Brakes	Meets ISO 7176-3: 2003	
Static Strength	Meets ISO 7176-8: 1998	
Impact Strength	Meets ISO 7176-8: 1998	
Fatigue Strength	Meets ISO 7176-8:1998	
Resistance to Ignition	Meets ISO 7176-16:1997	

A brief discussion of the non-clinical testing data that was submitted, referenced or relied on to demonstrate that the Subject Device is safe and effective, and whose performance meets the requirements of its user-defined acceptance criteria and intended uses:

Manual Wheelchair Model SY100-MA02 (02A & 02B) and Model SY100-MA06 (or other clients private labeling) meets performance requirements per ISO 7176-1:1999, ISO 7176-3: 2003, ISO 7176-8: 1998, and ISO 7176-16:1997. They are safe and effective, and their performances meet the requirements of their pre-defined acceptance criteria and intended uses.

A brief discussion of the clinical submitted, reference, or relied on in the premarket notification submission for a determination of substantial equivalence.

Clinical data is not needed for manual wheelchair cleared by the 510(k) process.

Substantial Equivalent Conclusions

Based on the comparison of intended use, design, materials, and performance, our Manual Wheelchair Model SY100-MA02 (02A & 02B) and Model SY100-MA06 (or other clients private labeling) are substantial equivalent to their predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 13, 2014

Zhejiang Jiafeng Electrical & Mechanical Co., Ltd.
c/o Charles Shen
Manton Business and Technology Services
5 Carey Street
Pennington, NJ 08534

Re: K132257
Trade/Device Name: Manual Wheelchair Model SY100-MA02 (02A & 02B) and Model SY100-MA06
Regulation Number: 21 CFR 890.3850
Regulation Name: Mechanical Wheelchair
Regulatory Class: Class I
Product Code: IOR
Dated: November 30, 2013
Received: December 3, 2013

Dear Charles Shen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Joyce M. Whang -S

for Carlos L. Peña, Ph.D., M.S.
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K132257

Device Name
Manual Wheelchair Model SY100-MA02 (02A & 02B) and Model SY100-MA06

Indications for Use *(Describe)*
The device is intended for medical purposes to provide mobility to persons restricted to a sitting position. It is designed for use indoors and outdoors, over smooth surfaces (all standard indoor flooring surfaces, concrete, asphalt and packed dirt) that are free of large obstacles and inclines greater than 8 degrees.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Joyce M. Whang -S

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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PRAStaff@fda.hhs.gov

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